

REMARKS

The Examiner issued a Non-Final Office Action dated November 2, 2006 in connection with the above-identified pending patent application. The Examiner indicated that claims 1-40 are rejected. In particular, the Examiner rejected claims 1-2, 4, 10-12, 14, 20-21, 26-29 and 33-37 under 35 U.S.C. §102(b) as being anticipated by EP 0792621 to *Uwaydah*, rejected claims 3 and 13 under 35 U.S.C. §103(a) as being unpatentable over *Uwaydah* and further in view of United States Patent No. 4,616,650 to *Green*, rejected claims 5-9, 15-19, 30-32 under 35 U.S.C. §103(a) as being unpatentable over *Uwaydah* and further in view of United States Patent No. 5,219,358 to *Bendel*, rejected claims 22-23 and 25 under 35 U.S.C. §103(a) as being unpatentable over *Uwaydah* and further in view of United States Patent No. 5,987,572 to *Schulsinger*, and rejected claim 24 under 35 U.S.C. §103(a) as being unpatentable over *Uwaydah* in view of United States Patent No. 5,578,044 to *Gordon*. The Examiner also rejected claims 1, 10, 21, 26 and 33 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, 19 and 25 of United States Patent No. 7,112,208.

Claims 1-40 were pending in this application. Claims 1, 3, 7, 10, 11 13-17, 21 and 33-40 have been amended, and claims 26-32 have been canceled without prejudice. In view of the amendments presented above, claims 1-25 and 33-40 are allowable, and the Examiner is respectfully requested to withdraw the rejections and issue a timely Notice of Allowance.

I. SPECIFICATION

The Examiner objected to the specification because of informalities. The informalities have been corrected, as recommended by the Examiner and thus, the Examiner is respectfully requested to withdraw the rejection.

II. REJECTIONS UNDER 35 U.S.C. §102

The Examiner rejected claims 1-4, 7, 9-16, 19, 20, 22-28, 30-32 and 36 under 35 U.S.C. § 102(b) as being anticipated by EP 0792621 to *Uwaydah*. The Examiner wrote that *Uwaydah*, in Figures 1 and 8, discloses an elongated tube 10a, a non-linear portion, a trocar 48 (figure 8), a linear slot, a malleable needle 18, and an apparatus for grasping comprising the second jaw, which has an aperture 12b. The Examiner also stated that *Uwaydah* also discloses a jaw pivotally coupled to the distal end of the handheld instrument for holding tissue as the needle portion and suture material enters the tissue.

Uwaydah discloses a clamping device having elongated channels through which a flexible needle carrying a suture may pass. The flexible needle, as shown in Figure 1, is inserted into the opening (12a) at the proximal end of the clamping device and is pushed out of the exit port (14a). In contrast, independent claims 1 and 10 have been amended, in relevant part, to state "the passageway having a linear slot in a side wall proximate to the distal end of the handheld instrument to receive the malleable needle portion within the passageway so that the malleable needle may be pushed through the passageway and into

tissue . . ." Similarly, independent claim 33 has also been amended to state "positioning the needle portion in a passageway of a handheld instrument by inserting the needle through a linear slot in a side wall of the passageway proximate to a distal end of the handheld instrument." The claimed slot facilitates easy insertion of the needle and suture into the claimed device proximate to the distal end. Inclusion of the linear slot proximate to the distal end enables the suture to be inserted with little movement of the force-supplying structure, thereby increasing the ease with which the handheld instrument may be used. The claimed slot also permits easy use of a needle having a short length that is usable with the claimed invention. Such a slot is not disclosed in *Uwaydah*. Thus, for at least this reason, claims 1, 10 and 33 and those claims depending therefrom, are allowable, and the Examiner is respectfully requested to withdraw the rejection.

Independent claim 21 is directed to a suture and has been amended to state that the suture "inelastically deforms in accordance with the off-axis distal end and remains in a deformed condition after being pushed through the hand held instrument," and claims 26-32 have been canceled without prejudice. In contrast, *Uwaydah* discloses a needle "similar to the one used for meniscal repair" (column 5, line 34) and discloses that the needle "must be long enough to extend all the way from the entrance port of one channel to the exit port of the other channel." (column 6, lines 12-15) *Uwaydah* does not disclose a suture that "inelastically deforms in accordance with the off-axis distal end and remains in a deformed

condition after being pushed through the hand held instrument." Thus, for at least this reason, claim 21 and those claims depending therefrom, are patentable.

III. CLAIM REJECTIONS UNDER 35 USC § 103

The Examiner rejected claims 3 and 13 under 35 U.S.C. 103(a) as being unpatentable over *Uwaydah* in view of United States Patent No. 4,616,650 to *Green et al.* The Examiner stated that *Uwaydah* fails to disclose a narrowing slot and that *Green et al.* discloses that a wider entrance area of a slot facilitates entry of an object. The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the slot wider at the entrance, thereby making it easier for the needle to enter the slot.

As previously set forth, *Uwaydah* discloses a clamping device having elongated channels through which a flexible needle carrying a suture may pass. The flexible needle, as shown in Figure 1, is inserted into the opening (12a) at the proximal end of the clamping device and is pushed out of the exit port (14a). In contrast, independent claims 1 and 10 have been amended to state "the passageway having a linear slot in a side wall proximate to the distal end of the handheld instrument to receive the malleable needle portion within the passageway so that the malleable needle may be pushed through the passageway and into tissue . . ." The claimed slot facilitates easy insertion of the needle and suture into the claimed device. Such a slot is not disclosed in *Uwaydah* or *Green*. In addition, claims 3 and

13 have been amended to state "further comprising a slit narrower than the linear slot in the side wall, wherein the slit extends from the linear slot to a distal end of the passageway and through the nonlinear portion enabling the suture material to extend from the slit as the needle is pushed through the nonlinear portion." Neither *Uwaydah* nor *Green* discloses a slit narrower than the linear slot enabling the suture material to extend from the slit. Thus, claims 3 and 13 are allowable for at least these reasons, and the Examiner is respectfully requested to withdraw the rejection.

The Examiner rejected claims 5-9, 15-19, 30-32 and 38-40 under 35 U.S.C. § 103(a) as being unpatentable over *Uwaydah* as applied to claims 1, 4, 10, 14, 26, 29, 33 and 37 and further in view of United States Patent No. 5,219,358 to *Bendel*. Claims 1, 10, 21 and 33, and those claims depending therefrom, are patentable for the reasons set forth above in Sections II and III. Thus, the Examiner is respectfully requested to withdraw the rejection.

The Examiner rejected claims 22-23 and 25 under 35 U.S.C. §103(a) as being unpatentable over *Uwaydah* and further in view of United States Patent No. 5,897,572 to *Schulsinger*. The Examiner also rejected claim 24 under 35 U.S.C. §103(a) as being unpatentable over *Uwaydah* and further in view of United States Patent No. 5,578,044 to *Gordon*. Claims 22-23 and 25 depend from claim 21, which is allowable for the reasons previously set forth. Therefore, claims 22-23 and 25 are allowable, and the Examiner is respectfully requested to withdraw the rejection.

IV. DOUBLE PATENTING REJECTION

The Examiner rejected claims 1, 10, 21, 26 and 33 on the grounds of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 11, 19 and 25 of United States Patent No. 7,112,208. The Examiner stated that although the claims are not identical, the claims are not patentably distinct from each other because they each recite a malleable needle portion, a handheld instrument, and a force-supplying structure. The Examiner indicated that the rejection may be overcome if the application and patent are commonly owned or the result of activities undertaken within the scope of a joint research agreement and a terminal disclaimer under 37 CFR 1.321(c) or 1.321(d) is timely filed. An executed terminal disclaimer under 37 CFR 1.321(c) is filed herewith. Thus, the Examiner is respectfully requested to withdraw the rejection.

IV. PETITION FOR ONE MONTH EXTENSION OF TIME

This is a Petition for a One Month Extension of Time pursuant to 37 CFR § 1.136. Please charge the fee in the amount of \$120.00 for a one (1) month extension of time pursuant to 37 CFR § 1.17(a)(1) and charge any underpayment or credit any overpayment to Deposit Account No. 50-0951. A duplicate copy of this communication is enclosed.

CONCLUSION

For at least the reasons given above, claims 1-25 and 33-40 define patentable subject matter and are thus allowable. Should the Examiner believe that anything further is necessary in order to place the application in better condition for allowance, the Examiner is respectfully requested to contact the undersigned representative at the telephone number listed below.

No fees in addition to the one-month extension of time are believed due; however, the Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, to Deposit Account No. 50-0951.

Respectfully submitted,



Michael K. Dixon
Reg. No. 46,665
AKERMAN SENTERFITT
222 Lakeview Avenue
Suite 400
West Palm Beach, Florida 33401-6183
(561) 653-5000